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ORIGINAL ARTICLE

Analysis of the performance of post-lingually deafened patients with Nurotron® Venus™ cochlear implants

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Abstract

Objective: The aim of this study was to analyze the safety and effectiveness of a new cochlear implant (CI) system developed in China, the Nurotron Venus device. *Material and methods:* Fifteen post-lingually deafened patients received Nurotron Venus CIs in our hospital. The safety and effectiveness of the devices were evaluated within 2 years after implantation. Patients' hearing thresholds were assessed. In addition, the speech perception performance of Nurotron Venus CI recipients was compared with that of 15 Cochlear Nucleus CI24 recipients. *Results and conclusion:* During 2 years of observation, all the Nurotron recipients used their devices regularly and effectively. The aided hearing thresholds of all the recipients were within the speech spectrum. The average scores of HOPE sentences and HOPE monosyllable words tests among Nurotron CI recipients were 82.88 ± 21.40% and 56.67 ± 9.77%, respectively. The average scores among Cochlear Nucleus CI24 recipients were 87.33 ± 14.44% and 52.8 ± 12.76%, respectively. There was no statistically significant difference in the speech test scores between these two groups when assessed using the t test. The Nurotron Venus cochlear implant system worked safely and effectively. The speech perception of Nurotron recipients was similar to that of the other CI system recipients.

Keywords: *Safety, effectiveness, auditory performance, speech perception*

Introduction

Multi-channel cochlear implants (CIs) are high-tech electronic products that can help severe to profoundly deafened patients restore or gain their hearing perception. During the last 40 years of clinical application and development, more than 380 000 deaf patients in the world have received CIs. According to the ear and hearing disorder survey protocol of WHO, Xingkuan Pu, et al. [1] conducted a relevant survey in China in 2005. The results showed that there were about 48 million hearing-impaired Chinese people, and the number of deaf newborns in China is about 20 000–30 000 per year. The technology of cochlear implantation was introduced to China about 20 years ago, and more than 20 000 Chinese people have benefited from it. For those who suffer from severe to profound sensorineural hearing loss, cochlear implantation is an effective approach for hearing rehabilitation. However, most of the CI products used in China are imported, and they are too expensive for most Chinese people to afford. The Nurotron Venus CI system, originally developed in the University of California Irvine and House Research Institute by Dr Fangang Zeng et al. [2–4], was introduced to China by Hangzhou Nurotron Biotechnology Co. Ltd in 2006. The research and development center of Nurotron is located in California, and the CI devices are manufactured in China. The Nurotron Venus CI system (Figure 1) produced in China is a relatively new device that has 24 intracochlear electrodes and two extracochlear electrodes, high stimulation rates (40 kHz), high data transmission rates (1 MB/s), multiple stimulation

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Figure 1. Nurotron Venus CI system.

modes, and four independent current sources. The major parameters of the CS-10A implant and the NSP-60B speech processor, which indicate the characteristics of Nurotron Venus CI system, are shown in Tables I and II. After several years of careful and successful verification both in the laboratory and in animals, this device was finally approved by the State Food and Drug Administration for application in post-lingually deafened volunteers. According to the clinical trial protocol, a total of 60 subjects all over China participated in this clinical trial from December 2009. They were all native Mandarin speakers and post-lingually deafened, and their ages were not younger than 6 years old.

As part of the clinical trial for this new device, 15 hearing-impaired patients received Nurotron Venus CIs in the Department of Otolaryngology-Head and Neck Surgery of our hospital. The safety and effectiveness of the device were evaluated in this study. In addition, the speech perception of Nurotron Venus CI recipients was compared with that of Cochlear Nucleus CI24 recipients.

Table I. Parameters of the Nurotron CS-10A implant.

Implant characteristics	Parameters
Material	Platinum, titanium, silicon
Electrodes	24 intracochlear electrodes and 2 extracochlear electrodes
Length of electrode array	20.5 mm
Interval of electrodes	0.85 mm
Volume of titanium housing	12.8 ml (56.4 × 33.0 × 6.9)
Bone-excavation volume	0.44 ml
Number of channels	24
Number of current sources	4
Wireless transmission frequency	16 MHz
Data transmission rate	1 MB/s
Total stimulation rate	40 kHz
Maximum current output	1.7 mA
Virtual channel capability	Yes
Telemetry capability	Yes

Table II. Parameters of the Nurotron NSP-60B speech processor.

Speech processor characteristics	Parameters
Wearing styles	Body-worn and ear-level
Audio input dynamic range	75 dB
Speech processing strategies	APS, CIS, VC (virtual channel)
Display mode of the volume and programs	LED lights
Water splash-proof	IP44
Battery	Rechargeable battery for both body-worn and ear-level, or two disposable AAA batteries for body-worn and three disposable zinc-air power batteries for ear-level

Materials and methods

Subjects

In the Nurotron group of the clinical trial, 15 post-lingually deafened patients, including 10 males and 5 females, received Nurotron Venus CI systems (including the CS-10A implant and the NSP-60B speech processor) in our hospital from March to April 2010 (Table III). Their average age was 25.4 ± 8.97 years, within the range 12–43 years. The duration of severe to profound hearing loss in these subjects was 7.27 ± 4.43 years on average. Their average preoperative hearing thresholds at four frequencies (0.5, 1, 2, 4 kHz) were 117.67 ± 6.23 dB HL, 117.33 ± 5.63 dB HL, 118.00 ± 3.68 dB HL, and 119.00 ± 3.87 dB HL, respectively. Among them, one subject had large vestibular aqueduct syndrome (LVAS), and the others had normal inner ear structure under imaging examination. In the Cochlear group, 15 post-lingually deafened patients, including 9 males and 6 females, underwent Cochlear Nucleus CI24 implantation in our hospital from March to December 2009 (Table IV). Their ages ranged from 18 to 56 years, with an average of 28.93 ± 13.07 years. The duration of severe to profound hearing loss was 7.47 ± 4.52 years on average. Among them, four subjects had LVAS, and the others had normal inner ear structure under imaging examination.

Methods

Observation of safety and stability of Nurotron Venus CI system. (1) For all the subjects, the location of the electrode array was investigated using cochlear view

Table III. Basic information for 15 Nurotron Venus CI recipients.

Recipient no.	Gender	Age at implantation (years)	Date of surgery	Duration of severe deafness (years)
1	Female	27	03.01.2010	7
2	Female	12	03.01.2010	9
3	Male	14	03.10.2010	3
4	Male	21	03.10.2010	7
5	Female	22	03.10.2010	3
6	Male	16	03.11.2010	10
7	Male	36	03.12.2010	15
8	Male	34	03.16.2010	2
9	Male	43	03.16.2010	3
10	Male	31	03.19.2010	1
11	Male	31	03.19.2010	11
12	Female	24	03.23.2010	13
13	Male	21	03.24.2010	9
14	Male	32	03.30.2010	4
15	Female	17	04.01.2010	12

X-ray examination after surgery. (2) To check the functions of their major organs, all the Nurotron recipients underwent blood tests and electrocardiograms at the approximate time points of 6 months, 1 year, and 2 years after surgery, which was required by the regulation of the State Food and Drug Administration. (3) All the Nurotron recipients were observed to see if there were any complications and side effects related to CIs or CI implantations. (4) The average duration that the Nurotron recipients used their CI devices each day was recorded.

Effectiveness of the Nurotron Venus CI system. (1) Aided hearing threshold test. The test was conducted in free field by using GSI 61 audiometer in a standard sound-proof booth. The aided thresholds at 0.5, 1, 2, and 4 kHz were assessed by using warble tones, and the

Table IV. Basic information for 15 Cochlear Nucleus CI24 recipients.

Recipient no.	Gender	Age at implantation (years)	Date of surgery	Duration of severe deafness (years)
1	Male	42	08.08.2009	15
2	Female	24	05.18.2009	10
3	Male	55	08.25.2009	3
4	Male	56	09.10.2009	2
5	Female	20	08.06.2009	10
6	Male	18	05.12.2009	1
7	Female	21	12.21.2009	8
8	Male	27	05.13.2009	8
9	Female	18	07.10.2009	3
10	Female	27	05.23.2009	13
11	Female	24	12.04.2009	4
12	Male	22	08.08.2009	7
13	Male	20	07.24.2009	4
14	Male	41	10.28.2009	10
15	Male	19	12.09.2009	14

settings of their speech processors were the same as those used daily.

(2) Open-set speech perception test. In this study 12 Nurotron Venus CI users performed the tests of sentences and monosyllable words 2 years after surgery. The results were compared with the scores achieved by Cochlear Nucleus CI24 users. Specifically, the speech processing strategy used by all the Nurotron recipients in this study was APS, i.e. advanced peak selection, a peak extraction strategy that select the largest outputs of filter bank. All the Cochlear recipients used ACE strategy in this study. The Mandarin speech test material, HOPE, was developed by the Auditory Implantation Center of the Department of Otolaryngology & Head and Neck Surgery of PLA General Hospital [5,6]. Each list of HOPE monosyllable words contains 25 monosyllable words and each list of HOPE sentence tests contains 10 sentences and 50 key words. All the tests were conducted by an open-set approach. The *t* test with SPSS software was used to analyze the results.

Satisfaction surveys. Satisfaction surveys on sound perception, communication skills, and the quality of life were conducted 2 years after implantation among Nurotron CI recipients.

Results

Safety of Nurotron Venus CI system

The post-surgery radiological results (Figure 2) showed that the electrode arrays in 15 Nurotron Venus CI recipients were all inserted inside the cochlea. No electrode migration, prolapse or displacement was observed. The results of the blood tests and electrocardiograms were in the normal range. No infection or rejection of the implants was reported. No complication related to the Nurotron Venus CI system occurred. Three of 15 recipients dropped out of the clinical trial program for personal reasons. The CI system worked well for all the remaining 12 implantees, and they used their devices during all their waking hours.

Aided hearing thresholds

The mean aided hearing thresholds of the 12 recipients ranged from 25 to 50 dB HL. The average thresholds at four frequencies (at 0.5, 1, 2 and 4 kHz) were 42.50 ± 3.37 dB HL, 40.00 ± 3.69 dB HL, 42.50 ± 3.99 dB HL, and 43.33 ± 4.92 dB HL, respectively. They were all within the range of speech spectrum.

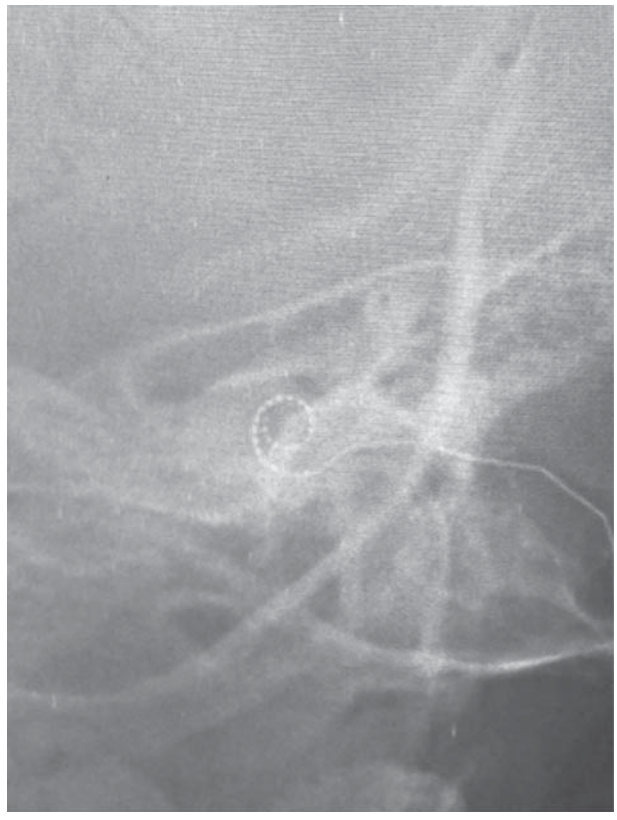

Figure 2. X-ray result after cochlear implantation (Zhang, female, left ear).

*Results of open-set speech perception tests (*Figure 3*)*

Two years after CI surgery, the average scores for HOPE sentence tests and monosyllable words tests among 12 Nurotron recipients were 82.88 ± 21.40% and 56.67 ± 9.77%, respectively.

The average scores for HOPE sentence tests and monosyllable words tests among 15 Cochlear recipients were 87.33 ± 14.44 and 52.8 ± 12.76%,

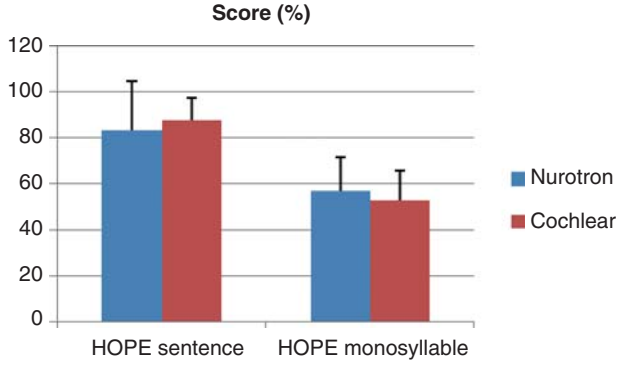

Figure 3. Speech perception scores of Nurotron Venus CI users and Cochlear Nucleus CI24 users. No statistically significant difference could be found between the two groups ($p > 0.05$).

respectively. The scores of the above tests from the two groups were in accordance with normal distribution. There were no statistically significant differences ($p > 0.05$, t test) in the scores for the speech tests between the two groups.

Satisfaction surveys

Of the 12 recipients who participated in the 2-year assessment, 10 recipients (83.34%) were satisfied with their outcomes, and the other two felt 'normal' with their outcomes. Their relationships with their families and friends were improved. Nine of them found new jobs or had better performance in their daily work since they could benefit from CIs. Two of them had significant improvement in their studies. Three of them were married to normal-hearing men, as they could communicate with their husbands with CIs. They felt much safer than before and it was more convenient for them to go shopping or go on a trip. Eight recipients could even use the telephone to simply communicate with others.

Cases lost during follow-up

During the 2-year follow-up of Nurotron Venus CI users, we lost contact with one recipient and two dropped out. Their circumstances were as follows. (1) Wu, male, 36 years old, received a CI on March 12, 2010. We failed to make contact with him 1 year after CI surgery. (2) Zang, male, 20 years old, received a CI on March 10, 2010. He declined to participate in clinical assessment from August 5, 2010 for family reasons. (3) Tong, male, 14 years old, received a CI on March 10, 2010. He did not participate in the 2-year assessment for personal reasons.

Discussion

After several decades of development, CI technology has been maturing. In fact, the outcomes of CIs were well documented in the last century [7–9]. Undoubtedly, the demand for CIs in China is extensive. However, the prices of imported CI devices are not affordable, and the choices left to those people suffering from severe hearing loss are relatively limited. Similar to other products, the Nurotron Venus CI system consists of two parts, the implant and the speech processor, which are programmed using NuroSound software. The parameters and the functions of this product seem to be comparable to others. If the long-term safety and outcomes could be tested and verified, the emergence of this product may have some significance for the local deaf patients and even for the whole CI industry.

The objective of this study was to analyze the safety and effectiveness of the Nurotron Venus CI system. For the sake of collecting information precisely and efficiently, post-lingally deafened adults are ideal subjects. They experienced aural and verbal communications before they were profoundly deafened. Therefore, they could benefit from CIs soon after the surgery and could communicate with clinicians more easily [10]. In addition, the duration of severe to profound deafness is an important factor as regards the outcome of cochlear implantation [11,12]. The duration of severe to profound deafness of all the patients in this study was less than 15 years.

During the 2 years of follow-up of Nurotron Venus CI system users, no complications related to the device were observed and all the CI systems worked well. The aided hearing thresholds were within the speech spectrum, indicating that the recipients were able to detect most of the speech sounds in daily life. There was no statistically significant difference in the speech perception scores between Nurotron CI users and Cochlear CI users.

Basically, the Nurotron CI recipients were satisfied with the outcomes of CI surgery. The improvements in hearing detection and speech perception are of great significance, and the most important goal of cochlear implantation is to help those deaf people return to the normal hearing world. According to surveys among Nurotron CI implantees, their quality of life improved significantly, including their daily life, study, and careers. In the present study, we found that post-lingually deaf CI users usually have high expectations for the outcomes, since they used to hear natural sounds before their deafness. Therefore, we should help post-lingually deafened people to understand the benefits and limitations of CIs and establish appropriate expectations for the outcomes.

Conclusions

During the 2-year observation period, the Nurotron Venus CI system produced in China worked safely and effectively. After implantation, all the recipients had better auditory performance and their quality of life was significantly improved. They all enjoyed the pleasant communication and the convenience obtained from their CI devices. According to the test results, the speech perception of Nurotron recipients was similar to that of the other system CI recipients. However, further long-term observations are needed.

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